

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of Elrod et al. : Group Art Unit: Not Yet known  
Application No.: 10/581,977 : Examiner: Not Yet known  
Filed: December 10, 2006 : Docket No. 53524AUSM1

For: USE OF CATHEPSIN S INHIBITORS FOR TREATING AN IMMUNE RESPONSE CAUSED BY ADMINISTRATION OF A SMALL MOLECULE THERAPEUTIC OR BIOLOGIC

Mail Stop: PCT  
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Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

In accordance with 37 CFR §1.56 and 1.97 through 1.98, Applicants wish to make known to the Patent and Trademark Office the references cited from a foreign patent office on the attached form PTO-1449 (copies enclosed).

As to any reference supplied, Applicants do not admit that it is "prior art" under 35 U.S.C. §102 or 103, and specifically reserve the right to traverse or antedate any such reference, as by a showing under 37 C.F.R. §1.131 or other method. Although the aforesaid references are made known to the Patent and Trademark Office in compliance with Applicants' duty to disclose all information they are aware of which is believed relevant to the examination of the above-identified application, Applicants believe that their invention is patentable.

This Information Disclosure Statement is being filed before the mailing of the first Office Action on the merits as described in 37 CFR 1.97(b). Therefore, it is believed that no fee is required under 37 CFR 1.97(b)(3). However, the Commissioner is hereby authorized to charge any additional fees required to facilitate the filing of this application to deposit account 02-2117. This is, however, not authorization to charge the issue fee.

Please acknowledge receipt of this Information Disclosure Statement and kindly make the cited references of record in the above-identified application.

Respectfully Submitted,  
BERLEX BIOSCIENCES  
Customer No. 27586

*Jacqueline S Larson*

Jacqueline S. Larson (Reg. No. 30,279)  
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Date: Oct. 13, 2006

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FORM PTO-1449 (REV.7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. <b>53524AUSM1</b>	APPLICATION NO. <b>10/581,977</b>
<b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>		APPLICANTS <b>Elrod et al.</b>			
		FILING DATE <b>December 10, 2004</b>	GROUP ART UNIT <b>Not Yet Known</b>		

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	US 6,608,030	Aug. 19. 03	Ploegh et al.			
	US 7,101,880	Sept. 05. 06	Graupe et al.			
	US2005/0182096	Aug. 18. 05	Link et al			
	US2003/232864	Dec. 18. 03	Link et al			

**FOREIGN PATENT DOCUMENTS**

	DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES      NO
	WO02/20485	Mar. 14. 02	PCT	
	WO03/029200	Apr. 10. 03	PCT	
	WO02/20002	Mar. 14. 02	PCT	
	WO04/083182	Sept. 30. 04	PCT	
	WO04/028521	Apr. 08. 04	PCT	
	WO05/028429	Sept. 17. 04	PCT	
	WO06/034006	Sept. 16. 05	PCT	
	WO04/00838	Dec. 31. 03	PCT	
	WO04/108661	Dec. 16. 04	PCT	
	WO02/098850	Dec. 12. 02	PCT	
	WO05/028454	Sept. 17. 04	PCT	
	WO05/058348	Dec. 10. 04	PCT	
	WO05/063742	Dec. 22. 04	PCT	
	WO05/074904	Jan. 31. 05	PCT	
	WO06/060494	Dec. 01. 05	PCT	
	WO00/55144	Sept. 21.00	PCT	
	WO01/19796	Mar. 22. 01	PCT	
	WO03/024924	Mar. 27.03	PCT	
	WO04/033445	Apr. 22. 04	PCT	

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<b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>		APPLICANTS <b>Elrod et al.</b>			
		FILING DATE <b>December 10, 2004</b>	GROUP ART UNIT <b>Not Yet Known</b>		
		WO03/097617	Nov. 27. 03	PCT	
		WO06/102423	Mar. 23. 06	PCT	
		WO01/19816	Mar. 22. 01	PCT	
		WO00/51998	Sept. 8. 00	PCT	
		WO02/069901	Sept. 12. 02	PCT	
		WO06/102535	Mar. 22. 06	PCT	
		WO06/060810	Dec. 01. 05	PCT	
		WO06/034004	Sept. 16. 05	PCT	
		WO06/102243	Mar. 17. 06	PCT	
		EP 1 516 877	Mar. 23. 05	EP	
		EP 0 623 627	Nov. 09. 94	EP	
7	Riese et al., "Cathepsin S Activity Regulates Antigen Presentation and Immunity." <i>Journal of Clinical Investigation, Pages 2351-2363, June 1998.</i>				
8	Saegusa et al., "Cathepsin S Inhibitor Prevents Autoantigen Presentation and Autoimmunity." <i>Journal of Clinical Investigation, Vol. 110, No.3, Pages 361-369, August 2002.</i>				
EXAMINER			DATE CONSIDERED		
<p>* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).</p>					

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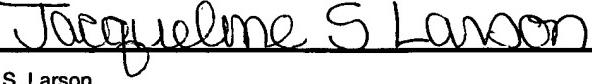
Application Number	10/581,977
Filing Date	December 10, 2004
First Named Inventor	Elrod et al.
Art Unit	Not Yet Known
Examiner Name	Not Yet Known

Attorney Docket Number 53524AUSM1

## ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
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Remarks		

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Berlex Biosciences.		
Signature			
Printed name	Jacqueline S. Larson		
Date	Oct. 13, 2006	Reg. No.	30,279

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Typed or printed name	Alishia L. Rowe-Babb	Date	10/13/06

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**Inventor:** Elrod et al.  
**Case No.:** 5352AUSM1  
**Serial No.:** 10/581,977  
**Filing Date:** December 10, 2004  
**Attorney or Agent:** Jacqueline S. Larson  
**Document(s):** Transmittal Form (1page)  
Form-1449 (2page)  
IDS w/ cited refs

**Date Sent to USPTO:** October 13, 2006

**Via First Class Mail**